IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

UNITED STATES OF AMERICA ex rel. **ELIZABETH A. COOLEY,** **Plaintiff** **v.** **ERMI, LLC f/k/a ERMI, INC.; THOMAS P. BRANCH, M.D.; CHUTE 15, INC.; ANTHRORESEARCH, LLC; ROBODIAGNOSTICS, LLC; and END RANGE OF MOTION IMPROVEMENT, INC.** **Defendants.**	**CASE NO.** _____ **FILED UNDER SEAL** **FALSE CLAIMS ACT, 31 U.S.C. §§ 3729, *ET SEQ*., ACTION** **JURY TRIAL DEMANDED**

COMPLAINT PURSUANT TO THE FALSE CLAIMS ACT,
31 U.S.C. §§ 3729, *ET SEQ*.

COME NOW, Plaintiff/Relator Elizabeth A. Cooley, by and through the undersigned counsel, and files this Complaint Pursuant to the False Claims Act, 31 U.S.C. §§ 3729, *et seq*. (hereinafter "Complaint"), and allege as follows:

I. INTRODUCTION

1. The allegations set forth herein relate to a longstanding and systemic scheme by ERMI LLC f/k/a ERMI, Inc. and its sole owner and shareholder, Thomas P. Branch, M.D., to defraud Federal health insurance and workers' compensation programs administered by the United States Department of Health and Human Services, the United States Department of Labor, and the United States Department of Veterans Affairs, through falsely overbilling and through violations of the Anti-Kickback Statute and the Stark Law. Defendants, moreover, have carried out their scheme while knowingly and willfully ignoring the requirements for enrollment as providers for the Department of Health and Human Services and the United States Department of Labor. Defendants' scheme and resulting false claims to Federal health insurance and workers' compensation programs have resulted in tens of millions in losses to the United States.

II. PARTIES, JURISDICTION, AND VENUE

2. Defendant ERMI LLC f/k/a ERMI, Inc. (hereinafter "Defendant ERMI"), is a Delaware limited liability company with its headquarters located at 2872 Woodcock Road, Atlanta, Fulton County, Georgia 30341, and its principal place of business and manufacturing location is located at 441 Armour Place, N.E., Fulton County, Atlanta, Georgia 30324.

3. Defendant Thomas P. Branch, M.D. (hereinafter "Defendant Branch") resides at 930 Lullwater Road, N.E., Atlanta, DeKalb County, Georgia 30307.

4. Defendant Chute 15, Inc. (hereinafter "Defendant Chute") is a Delaware corporation with its principal place of business located at Defendant Branch's residence, 930 Lullwater Road, N.E., Atlanta, DeKalb County Georgia 30307.

5. Defendant AnthroResearch, LLC (hereinafter "Defendant AnthroResearch") is a Delaware limited liability company with its principal office located at 2872 Woodcock Road, Atlanta, Fulton County, Georgia 30341.

6. Defendant RoboDiagnostics, LLC (hereinafter "Defendant RoboDiagnostics") is a Delaware limited liability company with its principal office located at 1104 Paris Road, Suite 201, Mayfield, Graves County, Kentucky 42066, and its principal place of business located at 441 Armour Place, N.E., Fulton County, Atlanta, Georgia 30324.

7. Defendant End Range of Motion Improvement, Inc. (hereinafter "E.R.M.I., Inc.") is incorporated in Florida, and its principal place of business is 1256 Vinetree Dr., Brandon, FL 33510.

8. Plaintiff/Relator Elizabeth A. Cooley ("Relator") is a resident of Forsyth County, Georgia.

9. Relator brings this action on behalf of the United States of America and herself.

10. Relator brings this action in the name of the United States based upon direct and unique information obtained by her during her period of employment by Defendant ERMI, and is an "original source" of the material information set forth herein.

11. Relator has made appropriate voluntary disclosures to the United States prior to the filing of this action as required by 31 U.S.C. § 3730(b)(2).

12. Jurisdiction and venue are proper in this Court.

III. FACTUAL ALLEGATIONS

A. Defendant ERMI LLC, Defendant Branch, and Relator

13. Defendant ERMI manufactures and leases a range of durable medical equipment (DME) for the purpose of assisting orthopedic patients to regain their range of motion.

14. Defendant ERMI manufactures and leases several different types of DME for use on the knee, shoulder, elbow, and "great toe." *See* https://www.ermi-motion.com/programs/. Each type of DME generally falls into one of two categories: a "flexionator" or an "extensionator". The "flexionator" helps restore flexion, or bending of the joint, while the "extenionator" works on regaining

"extension," or straightening the joint. While most devices are for movement in one direction ERMI's Shoulder Flexionator, helps restore movement in multiple directions, including external rotation, abduction, flexion, and internal rotation.

15. Defendant ERMI manufactures all of its DME at its manufacturing facility located at 441 Armour Place, N.E., Fulton County, Atlanta, Georgia 30324.

16. Defendant ERMI markets its DME and related support services to payors, physicians, physical and occupational therapists, nurse case managers and other healthcare professionals, and patients, as well as to patients eligible, or potentially eligible, for workers' compensation benefits, and to recipients of benefits from the United States Department of Veterans Affairs (the "VA"). Defendant ERMI promotes its DME and support services as Defendant ERMI's "program."

17. Defendant Branch is the founder of, Chief Executive Officer and Manager for, and a shareholder in Defendant ERMI. Defendant Branch is also the sole owner of Defendant Chute 15. Upon information and belief, Defendant ERMI is approximately 99% owned by Defendant Chute 15 and approximately 1% owned by Defendant Road to Provo. Defendant Branch is also a Board Certified orthopedic surgeon who practiced at University Orthopaedic Clinic (hereinafter "UOC") and has privileges at Dekalb Medical Center, Northside Medical Center, and Northlake Surgical Center. UOC has locations in Fulton and DeKalb Counties.

18. Upon information and belief, Defendant E.R.M.I., Inc. is approximately 99% owned by Defendant Chute 15 and approximately 1% owned by Defendant Road to Provo. Defendant E.R.M.I., Inc. is a DBA/foreign corporation registration for Defendant ERMI in the state of Florida because the name "ERMI" was taken by another entity. Defendant E.R.M.I., Inc. holds the relevant license for Defendant ERMI in the state of Florida, but is otherwise a shell. All employees in the state of Florida are employed by Defendant ERMI, LLC and all business activities are conducted by Defendant ERMI, LLC. Accordingly, ERMI, LLC and E.R.M.I., Inc. are collectively referred to herein as "ERMI".

19. From November of 2018 to October of 2019, Relator Cooley was the Chief Compliance Officer for Defendant ERMI.

20. On or about April 1, 2019, Defendant ERMI was reorganized pursuant to 26 U.S.C. § 368(a)(1)(F) in order to make Defendant ERMI more attractive to potential investors.

21. During the reorganization pursuant to Section 368(a)(1)(F), ERMI, Inc. became ERMI, L.L.C.

22. During the reorganization, Defendant ERMI transferred its robotics division to Defendant RoboDiagnostics LLC.

23. During the reorganization, Defendant ERMI transferred its research and development division to Defendant AnthroResearch LLC and nearly all of its cash to Defendant AnthroResearch LLC.

24. Defendant AnthroResearch and Defendant RoboDiagnostics are wholly or mostly owned by Defendant Chute, which is wholly owned by Defendant Branch.

B. Federal Health Insurance and Workers' Compensation Programs

1. Medicare

25. Medicare is a federal health insurance program for people who are 65 or older and certain other people. *See* https://www.medicare.gov/what-medicare-covers/your-medicare-coverage-choices/whats-medicare. Medicare Part B (Medical Insurance) covers certain doctors' services, outpatient care, medical supplies, and preventive services. *Id*. The Medicare program is administered by the Centers for Medicare & Medicaid Services (CMS), which is part of the United States Department of Health and Human Services (HHS).

26. The Medicare program defines DME as equipment:

> [F]urnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
>
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> (3) Is primarily and customarily used to serve a medical purpose.
>
> (4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

27. The Medicare program pays for DME, prosthetics and orthotics (DMEPOS), including a separate payment for maintenance and servicing of such items. *See* 42 C.F.R. §§ 414.210(a), (e).

2. The Federal Employees' Compensation Act ("FECA")

28. FECA, as amended 5 U.S.C. §§ 8101 *et seq*., "provides for the payment of workers' compensation benefits to civilian officers and employees of all branches of the Government of the United States." 20 C.F.R. § 10.0. FECA is administered by the Division of Federal Employees' Compensation ("DFEC") of the Office of Workers' Compensation Programs ("OWCP") of the United States Department of Labor (OWCP). *See* OWCP Publication CA-810, Injury Compensation for Federal Employees, § 1-3 (Rev. 2009) (OWCP Publication CA-810).

29. FECA provides coverage for "medical services, appliances or supplies" which a qualified physician prescribes or recommends and which OWCP considers necessary to treat the work-related injury. *See* 20 C.F.R. § 10.310(a); *see also* DFEC PM, FECA Part 3, §§ 3-0300.1 & 3-0400.3c(3).

3. Veterans' Administration Benefits

30. The VA is an executive department of the United States which administers the laws providing benefits and other services to veterans and the dependents and the beneficiaries of veterans. *See* 38 U.S.C. §§ 301(a).

31. The VA fills prescriptions written by eligible providers for covered veterans for DMEPOS constitutes part of the VA's medical benefits package. *See* 38 C.F.R. §§ 17.38(a)(1)(viii) & 17.4025(b)(4).

4. Defendants and Federal Health Insurance and Workers' Compensation Programs

32. Defendant ERMI generates in excess of $40,000,000 in revenue each year. Defendant ERMI was recently valued at approximately $130,000,000. Upon information and belief, prior to Relator's departure, Defendant ERMI had received approximately $39,075,000 in gross revenue over the previous twelve months, over $30 million of which, came from various federal agencies, including Medicare, the VA and OWCP.

33. Defendant ERMI receives most of its revenue from workers' compensation funds, the VA, and government employee funds, including OWCP and Medicare.

34. Defendant ERMI claims that its "program" has been used in over 100,000 cases.

C. Defendants' False Overbilling of the Department of Labor and the VA

35. Defendant ERMI has used the following Pricing, Data Analysis and Coding (PDAC)-Medicare Contractor DMEPOS Codes for its DME to submit claims to, and receive reimbursement from, OWCP and the VA:

Product	Code(s)	Maximum Allowable Medicare Charges	Charged by ERMI
Knee Mobilizer/Flexionator	E1399 E1811	per agreement $150.95/month	VA: $77.00/day OWCP: $115.00/day
Shoulder Extensionator	E1841	$509.84/month	VA: $77.00/day OWCP: $115.00/day

36. A typical shoulder patient will use the ERMI Shoulder Extensionator for 60 days, being two consecutive 30-day prescriptions. ERMI would thus charge the VA $4,620 and OWCP $6,900. By comparison, current Healthcare Common Procedural Coding System (HCPCS) codes for shoulder extension/flexion devices, DMEPOS Codes E1840 and E1841, carry a maximum monthly reimbursement of $526.26.

37. A typical knee patient will likewise use the ERMI Knee Mobilizer/Flexionator for 60 days, being two consecutive 30-day prescriptions. ERMI would thus charge the VA $4,620 and OWCP $6,900. By comparison, current Healthcare Common Procedural Coding System (HCPCS) codes for knee

extension/flexion devices, DMEPOS Codes E1810 through E1812, carry a maximum monthly reimbursement of $144.74.

38. Defendants have submitted numerous false claims to VA containing falsely inflated charges of up to $3,567.48 for 60 days usage of the shoulder devices and $4,330.52 for the knee devices.

39. Defendants have submitted numerous false claims to OWCP containing falsely inflated charges of up to $5,847.48 for 60 days usage of the shoulder devices and $6,599.52 for the knee devices.

40.

41. In or around early December 2018, Relator attended a meeting with Defendant Branch, Mikael Ohman, and Defendant ERMI's Sales Directors. Relator warned those at the meeting that Defendant ERMI needed to prepare itself for a potential audit. During the meeting, Defendant Branch indicated, in effect, that Defendant ERMI had an agreement or arrangement with DOL or the OWCP to bill in this manner.

42. Following the December 2018 meeting, Relator looked for an alleged agreement or arrangement with DOL and/or the OWCP, but never found any evidence for any such alleged agreement or arrangement, either written or oral.

D. Defendants' Violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b

43. The Anti–Kickback Statute, 42 U.S.C. § 1320a-7b, states that whoever knowingly and willfully solicits, receives, offers, or pays any remuneration, including any kickback, bribe, or rebate, in return for referring an individual for the furnishing of any item or service, or for the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and shall be fined up to $100,000. *See* 42 U.S.C. § 1320a-7b(b).

44. Defendant ERMI is not in network with any commercial health insurers. All of Defendant ERMI's remuneration comes from Federal health care programs.

45. Defendant ERMI often gives its DME at no charge to patients with commercial health insurance, at the patients' physicians' request.

46. Defendant ERMI gives its DME at no charge to patients with commercial health insurance in exchange for the patients' physicians referring other patients under Federal health care programs to Defendant ERMI.

47. On or about June 14, 2019, Nathalie Moretz, Defendant ERMI's Director of Sales for the West Region, stated in an e-mail that many of Defendant ERMI's sales representatives tell doctors that their patients will receive a free DME device if

commercial insurance will not pay for the device, in order to get more federal business for Defendant ERMI.

48. Upon information and belief, Marc Cortez, former Vice President of Sales for Defendant ERMI, made payments to workers' compensation attorneys in exchange for the attorneys' referral of business to Defendant ERMI.

49. Defendant ERMI submitted claims to Medicare, OWCP, and the VA that were generated from paying or offering illegal remuneration in violation of the Anti–Kickback statute.

E. Defendants' Evasion of Medicare's and FECA's State Licensure Requirements

50. Medicare requires all providers and suppliers to make various certifications in order to enroll and maintain active enrollment status, including certification of compliance with Federal and State licensure, certification, and regulatory requirements, as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare. *See* 42 C.F.R. § 424.516.

51. Under FECA, providers who enroll with OWCP or one of its designated bill processing agents certify that they satisfy all applicable Federal and State licensure and regulatory requirements that apply to their specific provider or supplier type, and are required to maintain documentary evidence indicating that the provider satisfies the requirements *See* 20 C.F.R. § 10.800(a).

1. State Licensing, Permitting, and Registration of DME Manufacturers, Sellers, Distributors, Suppliers, or Providers

52. The State of Alabama requires that home medical equipment services providers be licensed annually by the Alabama Board of Home Medical Equipment. *See* Ala. Code § 34-14C-4(a). A provider of home medical equipment services with a principal place of business outside the state must maintain at least one physical location within the state, each of which must be licensed. *Id*.

53. The State of Arizona provides that durable medical equipment permits may be issued by the Arizona State Board of Pharmacy. *See* Ariz. Rev. Stat. Ann. § 32-1930(A)(3).

54. The State of Arkansas proscribes any person or entity from selling or renting or offering to sell or rent directly to patients in the state any home medical equipment unless the person or entity is licensed by the Arkansas State Board of Pharmacy. *See* Ark. Code Ann. § 17-92-902(a). A separate license is required for each facility directly or indirectly owned or operated within the state. *See* Ark. Code Ann. § 17-92-902(b)(2).

55. The State of California prohibits an out-of-state home medical device retail facility from selling or distributing prescription devices in the state through any person or media other than a licensed wholesaler, unless the facility registers as an out-of-state home medical device retail facility. *See* Cal. Health & Safety Code §

111656.7(a). Furthermore, persons acting as principal or agent for any out-of-state home medical device retail facility may not conduct the business of selling or distributing prescription devices within the state without registering with the California Department of Public Health. *See* Cal. Health & Safety Code § 111656.8(a).

56. The State of Colorado requires that, in order to do business in Colorado, a durable medical equipment supplier must be licensed by the Colorado Secretary of State. *See* Colo. Rev. Stat. Ann. § 24-21-115(2)(a).

57. The State of Connecticut prohibits manufacturers of devices from operating in the state until they have received a certificate of registration issued by the Connecticut Commissioner of Consumer Protection. *See* Conn. Gen. Stat. § 21a-70(b). A separate certificate is required for each location existing in the state and for each location existing outside of the state that distributes products into the state. *Id*.

58. The District of Columbia proscribes a person from engaging in distributing, manufacturing, importing, or vending medical devices in the District of Columbia unless the person has a valid license from the District of Columbia Department of Health. *See* D.C. Mun. Regs. § 10203.1. Each person engaged in the distributing, manufacturing, importing, or vending medical devices in the District must apply for

a license. *See* D.C. Municipal Regulations § 10203.3. Each place of business in the District for the purpose of medical device manufacturing, importing, or vending must be licensed by the D.C. Department of Health. *See* D.C. Mun. Regs. §§ 10203.4, 10203.5.

59. The State of Florida mandates that any person or entity that holds itself out to the public as providing home medical equipment and services or accepts physician orders for home medical equipment and services is subject to licensure. *See* Fla. Stat. Ann. § 400.93(1). Any locations that sell, rent, or distribute, or offer to sell or rent to or for a consumer any home medical equipment require a license from the Florida Agency for Health Care Administration (AHCA), including any locations out of state offering to sell or rent home medical equipment requiring services to consumers in Florida. *See* Fla Admin. Code § 59A-25.002(1).

60. Beginning in 2017, the State of Georgia required that any person who supplies durable medical equipment to a consumer and submits a claim for reimbursement by a third party, either directly or through a contractual arrangement, must possess a durable medical equipment supplier license issued by the Georgia State Board of Pharmacy. *See* Ga. Code Ann. § 26-4-51(a). The Board furthermore issues licenses to a Medicare enrolled out-of-state manufacturers or wholesale

distributors which provide durable medical equipment directly to consumers. *See* Ga. Code Ann. § 26-4-51(c).

61. The State of Illinois provides that no entity shall provide or hold itself out as providing home medical equipment and services in connection with its profession or business, without a license issued by the Illinois Department of Financial and Professional Regulation. *See* 225 Ill. Comp. Stat. Ann. § 51/15(a).

62. The State of Indiana requires a person seeking to provide home medical equipment services in Indiana to apply to the Indiana Board of Pharmacy for a license. *See* Ind. Code Ann. § 25-26-21-6(a). A provider must obtain a license for each location in Indiana from which the provider provides home medical equipment services. *See* Ind. Code Ann. § 25-26-21-8(a).

63. The State of Kansas enjoins any person from selling or leasing or offering for sale or lease durable medical equipment without first obtaining a registration from the Kansas State Board of Pharmacy. *See* Kan. Stat. Ann. § 65-1643(m).

64. The State of Louisiana provides that no person or other entity shall sell, rent or provide, or offer to sell, rent or provide, directly or indirectly, any durable medical equipment to consumers in the state until the person has obtained a durable medical equipment permit from the Louisiana Board of Pharmacy. *See* 46 La.

Admin. Code § LIII-2403(A). Providers are required to establish suitable facilities to house the equipment. *See* 46 La. Admin. Code § LIII-2405(B).

65. The State of Maryland requires that providers of DME shall meet licensing requirements of the Maryland Department of Health. *See* Code Md. Regs. §§ 10.09.12.02, 10.09.36.02.

66. The State of Mississippi prohibits any person, business, or entity inside or outside the state from selling, renting, or providing, or offering to sell, rent or provide, any home medical equipment directly to patients in the state, unless such person, business or entity first obtains a Medical Equipment Supplier Permit from the Mississippi Board of Pharmacy. *See* Miss. Code Ann. § 73-21-108(2)(a). A permit is required for each facility location directly or indirectly owned or operated in the state. *See* Miss. Code Ann. § 73-21-108(2)(c).

67. The State of Nevada provides that an applicant for a license to engage in business as a medical products provider must submit an application to the Nevada State Board of Pharmacy, including applicants out-of-state. *See* Nev. Admin. Code §§ 639.6942(1), 639.6944. Medical products providers must furthermore maintain a suitable physical location, other than a residence, at which the provider can: store inventory, repair or service any equipment, and keep all current records related to

the business of the medical products provider. *See* Nev. Admin. Code § 639.6946(1)(e).

68. The State of North Carolina requires that each place, whether located in the state or out-of-state, where devices or medical equipment are dispensed or delivered to users in the State, shall register annually with the North Carolina Board of Pharmacy. *See* N.C. Gen. Stat. Ann. § 90-85.22.

69. The State of Ohio proscribes persons from providing home medical equipment services unless the person holds a valid license or certificate of registration issued by the Ohio Board of Pharmacy. *See* Ohio Rev. Code Ann. § 4752.02(A). A person intending to provide home medical equipment services from more than one facility shall apply for a separate license or certificate of registration for each facility. *See* Ohio Rev. Code Ann. § 4752.03(B).

70. The State of Oregon enjoins "drug outlets" from operating in the State until a certificate of registration has been issued to the facility by the Oregon State Board of Pharmacy. *See* Or. Rev. Stat. Ann. § 689.335(1). "Drug" is defined as articles used for the treatment of disease or "intended to affect… any function of the body of humans…," and "drug outlet" means any "manufacturer, mail-order vendor or other establishment with facilities located within or out of this state that is engaged

in dispensing, delivery or distribution of drugs within this state." Or. Rev. Stat. Ann. §§ 689.005(11), (13).

71. The Commonwealth of Pennsylvania requires that every person who manufactures, distributes or retails devices within the Commonwealth or proposes to engage in the manufacture, distribution or retail sale devices within the Commonwealth to obtain annually a registration from the Pennsylvania Department of Health. *See* 28 Pa. Admin. Code § 25.113(a). Furthermore, every manufacturer or distributor of devices not operating an establishment within the Commonwealth must either obtain a registration or maintain with the Secretary of Health an up-to-date listing of the names and addresses of its representatives operating within the Commonwealth. *See* 28 Pa. Admin. Code § 25.113(c).

72. The State of Tennessee requires that home medical equipment providers shall be licensed by the Tennessee Board for Licensing Health Care Facilities. *See* Tenn. Code Ann. § 68-11-226(a). State regulations provide that no person, partnership, association, corporation, or state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate, or maintain in the state any home care organization providing home medical equipment without having a license. *See* Tenn. Comp. R. & Regs. § 1200-08-29-.02(a).

73. The State of Texas mandates that a person may not operate as a distributor or manufacturer of devices in this state unless the person has a license from the Texas Department of State Health Services for each place of business. *See* Tex. Health & Safety Code Ann. § 431.272(a).

74. The Commonwealth of Virginia provides that any person or entity desiring to obtain a permit as a medical equipment supplier shall file an application with the Virginia Board of Pharmacy. *See* 18 Va. Admin. Code § 110-20-630.

2. Defendants' Evasion of State Licensure Requirements

75. Defendant ERMI ships its extensionators directly to patients from its manufacturing facility in Atlanta. The patients ship the extensionators back to Defendant ERMI's manufacturing facility when the patients are finished using the devices.

76. However, since Defendant ERMI's flexionators (hereinafter "flexionator DME") are much larger and heavier than Defendant ERMI's extensionators, the flexionator DME cannot be shipped directly to patients. Defendant ERMI has employees deliver its flexionator DME directly to patients. Defendant ERMI's employees set up the flexionator DME for the patients, and instruct the patients on the use of the flexionator DME.

77. The vast majority of Defendant ERMI's flexionator DME is delivered to patients outside of the State of Georgia. During the time of Relator's employment with ERMI, it did business in 17 states as well as the District of Columbia. Defendant ERMI employs employees and sales representatives in these states.

78. In Defendants' desire to maximize Defendants' financial gain, Defendants ignore State licensing, registration, permitting, or certification requirements. Defendants do not want to incur the cost of hiring counsel to comply with state licensing, registration, permitting, certification, and inspection requirements.

79. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in Alabama without a license from the Alabama Board of Home Medical Equipment.

80. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in Arizona without a license from the Arizona State Board of Pharmacy, or with an expired or invalid license.

81. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in Arkansas without a license from the Arkansas State Board of Pharmacy, or with an expired or invalid license.

82. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in California without registering with the California Department of Public Health.

83. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in Colorado without a license from the Colorado Secretary of State, or with an expired or invalid license.

84. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in Connecticut without a certificate from the Connecticut Commissioner of Consumer Protection, or with an expired or invalid license.

85. Defendant ERMI provides, supplies, or distributes Defendants' flexionator DME in the District of Columbia without a license from the District of Columbia Department of Health.

86. For the six years preceding the filing of this action, Defendant ERMI has only maintained a license issued by the Florida AHCA in the name of E.R.M.I, Inc. for two periods of time, from October 13, 2016 through October 12, 2018, and from November 1, 2019 through the current date. At all other times, neither ERMI nor E.R.M.I, Inc. had a license issued by the Florida AHCA.

87. In addition, the 2016 license which was issued by the Florida AHCA to E.R.M.I., Inc. was obtained based on material misrepresentations in the applications submitted by ERMI, including but not limited to the following:

a. ERMI noted on the application that all equipment was stored at ERMI's home office in Atlanta, Georgia. This representation was false because ERMI knew that its sales representatives in Florida stored equipment in their garages and/or rented storage facilities for storage, expenses for which ERMI reimbursed the employees;

b. ERMI falsely claimed that maintenance on equipment was performed at ERMI's home office in Atlanta, when in fact, ERMI's employees in Florida performed whatever maintenance was required;

c. ERMI falsely represented that "no delivery personnel hired as yet." Prior to the submission of the 2016 application, ERMI was doing business in Florida and employed delivery personnel to set up patients with product in the home and to provide training;

d. ERMI falsely denied that equipment would be stored at locations in Florida.

88. In November of 2018, ERMI learned that the license issued by Florida AHCA had lapsed when the human resources department attempted to run an AHCA

background check on an employee in Florida. It thus became necessary to file a renewal application. However, that process was delayed because Defendant Branch was charged with misdemeanor battery in early 2019 based on an altercation he had with a female bank teller in Dekalb County, Georgia. The application was not filed until June 13, 2019, after Branch had completed the pre-trial diversion process that had been agreed to as part of his plea deal with the local solicitor's office. The application was signed by Relator as being true and correct.

89. At the time Relator signed the application, it was based on information provided to her by executives at ERMI, including Defendant Branch. Relator believed the information she was provided and believed the application to be true and correct. Relator subsequently learned that much of the information that was provided to her was false and that the application contained material misrepresentations, including but not limited to the following:

a. While the application did list a number of employees who were residents of Florida, several Florida resident employees names were withheld because those particular employees could not pass the required level 2 background check;

b. ERMI noted on the application that all equipment was stored at ERMI's home office in Atlanta, Georgia. This representation was false

because ERMI knew that its sales representatives in Florida stored equipment in their garages and/or rented storage facilities for storage, expenses for which ERMI reimbursed the employees;

c. ERMI falsely claimed that maintenance on equipment was performed at ERMI's home office in Atlanta, when in fact, ERMI's employees in Florida performed whatever maintenance was required

90. At all times in the six years prior to filing this Complaint, ERMI has provided, supplied, or distributed Defendants' DME in Florida without a license from the Florida AHCA, or with an invalid license obtained by making material misrepresentations on its applications.

91. Defendant ERMI provided, supplied, or distributed Defendants' DME in Georgia without a license from the Georgia State Board of Pharmacy until January 7, 2020.

92. Defendant ERMI provides, supplies, or distributes Defendants' DME in Illinois without a license from the Illinois Department of Financial and Professional Regulation.

93. Defendant ERMI provides, supplies, or distributes Defendants' DME in Indiana without a license from the Indiana Board of Pharmacy, or with an expired or invalid license.

94. Defendant ERMI provides, supplies, or distributes Defendants' DME in Kansas without a license from the Kansas State Board of Pharmacy.

95. Defendant ERMI provides, supplies, or distributes Defendants' DME in Louisiana without a permit from the Louisiana Board of Pharmacy, or with an expired or invalid permit.

96. Defendant ERMI provides, supplies, or distributes Defendants' DME in Maryland without a license from the Maryland Department of Health.

97. Defendant ERMI provides, supplies, or distributes Defendants' DME in Mississippi without a permit from the Mississippi Board of Pharmacy.

98. Defendant ERMI provides, supplies, or distributes Defendants' DME in Nevada without a license from the Nevada State Board of Pharmacy, or with an expired or invalid license.

99. Defendant ERMI provides, supplies, or distributes Defendants' DME in North Carolina without registering with the North Carolina Board of Pharmacy, or with an expired or invalid registration.

100. Defendant ERMI provides, supplies, or distributes Defendants' DME in Ohio without a license or certificate from the Ohio Board of Pharmacy.

101. Defendant ERMI provides, supplies, or distributes Defendants' DME in Oregon without obtaining a certificate from the Oregon State Board of Pharmacy, or with an expired or invalid certificate.

102. Defendant ERMI provides, supplies, or distributes Defendants' DME in Pennsylvania without registering with the Pennsylvania Department of Health, or with an expired or invalid registration.

103. Defendant ERMI provides, supplies, or distributes Defendants' DME in Tennessee without a license from the Tennessee Board for Licensing Health Care Facilities, or with an expired or invalid license.

104. Defendant ERMI provides, supplies, or distributes Defendants' DME in Texas without a license from the Texas Department of State Health Services.

105. Defendant ERMI provides, supplies, or distributes Defendants' DME in Virginia without a permit from the Virginia Board of Pharmacy.

106. Defendant ERMI continues to enroll as a provider or supplier for Medicare and OWCP while falsely certifying that Defendant ERMI is in compliance with applicable state licensure, certification, and regulatory requirements. Defendant ERMI submits claims for reimbursement, and is reimbursed by, Medicare and OWCP while in willful non-compliance with state licensure, certification, and regulatory requirements.

107. Defendant ERMI stores its DME in rental storage units, on private residential properties, or in sales representatives' vehicles in all or many of the states referenced in the preceding paragraphs.

108. In January of 2019, the Controller for Defendant ERMI sent an electronic mail to Relator to which were attached bills for storage units.

109. Defendant ERMI knowingly and willfully does not inform state, county, or local authorities that it is storing its DME within their jurisdictions, and does not subject its storage sites for its DME to licensing, registration, permitting, certification, or inspection.

110. Defendant Branch repeatedly refused to authorize hiring counsel to assist in obtaining state licenses, registrations, permits, or certification. Defendant ERMI continually ignored Relator's advice concerning compliance with state licensing, registration, permitting, certification, and inspection requirements.

111. Repeatedly in July 2019, Relator was threatened Defendant Branch that she would be fired and defamed by him if Relator made statements to licensing authorities or others that Defendant Branch did not approve of.

112. Defendant Branch directed employees of Defendant ERMI to state, in effect, that all of Defendant ERMI's DME was shipped into, and out of, Atlanta.

113. Defendant ERMI refused to give its Compliance Department authority to comply with state licensing, registration, permitting, certification, and inspection requirements.

114. Defendant ERMI prohibited its Compliance Department to investigate company practices and behaviors, to audit effectively, or to enforce standards.

115. Defendant ERMI prohibited its Compliance Department from communicating with the Sales Department as a whole without first notifying Defendant ERMI's senior leadership and getting the approval of Sales Leaders.

116. Repeatedly, in person and by email, Defendant Branch told Sales representatives that the compliance rules did not apply to them, and that they did not need to follow the compliance program.

117. Defendant Branch directed that meetings of officers and employees of Defendant ERMI not be recorded.

118. Doug Easley, National Sales Director for Defendant ERMI, bullied Relator Cooley concerning her compliance advice and efforts.

119. On or about July 26, 2019, the Florida AHCA sent Defendant ERMI a Notice of Intent to Deem Initial Application Incomplete and Withdrawn From Consideration (hereinafter "Notice"). The Notice stated that Defendant ERMI could

not engage in business in the State of Florida without having physical locations in the State of Florida which were licensed and inspected.

120. Defendant ERMI falsely informed the Florida AHCA that all of its DME was shipped out of Defendant ERMI's principal place of business in Atlanta, and that none of its DME was stored in Florida, except very rarely and on a temporary basis.

121. On August 1, 2019, Relator learned that Defendant Branch had directed that Defendant ERMI's legal counsel communicate with him via telephone or text message only in order to prevent Relator from providing accurate information to counsel.

122. Notwithstanding ERMI's lack of being licensed in those states described above, ERMI provided DME to patients in those states and ERMI submitted claims to Medicare, OWCP, and the VA for reimbursement.

F. Defendants' Violations of the Stark Law, 42 U.S.C. § 1395nn(a)

123. Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn, also known as the physician self-referral law, or "Stark Law," prohibits physicians with a financial relationship with an entity from making referrals to the entity for the furnishing of designated health services for which payment may be made under Medicare, and from presenting a claim or billing any individual, third party payor, or other entity

for designated health services furnished pursuant to such referral. *See* 42 U.S.C. § 1395nn(a).

124. A number of exceptions to the Stark Law exist, including referrals between a lessee and lessor of office space, provided that various conditions are met. *See* 42 U.S.C. § 1395nn(e)(1)(A); 42 C.F.R. § 1001.952(b).

125. Until 2012, Defendant ERMI had a lease agreement for office space with a company owned and controlled by Defendant Branch.

126. Upon information and belief, the lease agreement between Defendant ERMI and Defendant Branch expired in 2012, and was not renewed.

127. On or about June 4, 2019, Relator had a telephone conference with Defendant ERMI's legal counsel concerning the possibility of whether Defendant Branch had referred any Medicare patients to Defendant ERMI after the lease agreement between Defendant ERMI and Defendant Branch expired in 2012.

128. Defendant Branch became angry with counsel and Relator for making the inquiry and told counsel and Relator not to look into the matter any further.

129. Upon information and belief, since 2012, Defendant ERMI has submitted claims to Medicare that were generated from illegal referrals from Defendant Branch and UOC in violation of the Stark Law.

G. Defendants' False Claims Based Upon Lack of Medical Necessity

130. For the purposes of Medicare, all DMEPOS must be supported by medical necessity, and a DMEPOS supplier must maintain documentation of medical necessity from the treating practitioner. *See* 42 C.F.R. § 410.38(d)(3)(i).

131. Continued use of DME must be supported by medical necessity. *See* 42 C.F.R. § 414.230(b)(1).

132. All CMS-1500 Forms require a physician to certify under Medicare and FECA that the services shown on the form are medically indicated and necessary for the health of the patient and were personally furnished by the physician or were furnished incident to the physician's professional service by his or her employee under the physician's immediate personal supervision. *See* CMS-1500 Form.

133. The VA covers DME based upon "a determination of feasibility and medical need." *See* 38 C.F.R. § 17.150.

134. Defendant ERMI always charges Medicare, OWCP, and the VA for the maximum amount of time for its DME. Defendant ERMI bills OWCP for 16 weeks of usage of its DME for each patient, even though Defendant ERMI's own research shows that the average patient regains full range of motion in approximately ten weeks.

135. Relator informed Defendant ERMI's senior management that Defendant ERMI would have to confirm whether extended use of its DME was supported by medical necessity. Nathalie Moretz, Defendant ERMI's Director of Sales for the West Region, told Relator that Defendant ERMI's DME has a four month, or 16 week, program that Defendant ERMI would never bill federal health insurance or workers' compensation programs for a shorter period of time. Defendant ERMI prepares its annual budget assuming that Defendant ERMI will receive full payment for four months for every device authorized by OWCP.

136. Brad Caire, a Sales Representative for Defendant ERMI in New Orleans, Louisiana, had approximately ten to 12 physicians who would prescribe Defendant ERMI's DME for all of their patients. Caire's physicians generated approximately $1,000,000 in revenue each year for Defendant ERMI.

137. Defendant ERMI never inquired whether the DME prescribed by Caire's physicians was supported by medical necessity. When Caire was informed that he would be required to provide evidence of medical necessity for the prescriptions, in or around mid-July, 2019, he resigned from Defendant ERMI. Senior management for Defendant ERMI instructed Caire not to speak with Relator.

138. Following his resignation, Caire continued to solicit prescriptions from the physicians for Defendant ERMI's DME, and was compensated by Defendant ERMI.

H. Other False Claims by Defendants to Medicare, the Department of Labor, and the VA

139. All claims to Medicare, OWCP, or the VA must be certified as true, accurate, and complete. *See* Health Insurance Claim Form, CMS-1500 (HCFA-1500), OWCP-1500.

140. On or about July 12, 2019, a member of the Compliance Department found eight (8) boxes of compliance material for Defendant ERMI in a storage area. Relator had repeatedly requested the material from Defendant ERMI's senior management and Compliance Department personnel.

141. Relator reviewed the material and found evidence that Defendant ERMI had altered delivery tickets for its DME for the purpose of submitting false claims to Medicare, OWCP, and the VA.

142. Relator also found in the material evidence of pervasive Medicare requests for repayment from Defendant ERMI on the grounds that a patient had been admitted to a skilled nursing facility (SNF).

143. Terry Holley, an employee of Defendant ERMI, would routinely add items which had not been prescribed by a physician to claims submitted to the VA. The VA complained about the claims submitted by Holley. However, Defendant ERMI continued to employ Holly for approximately an additional 18 months.

I. **Other Conduct by Defendants**

144. At the early December 2018 meeting, Relator told the persons present at the meeting that Defendant ERMI needed to prepare itself for a potential audit. Doug Easley and Jennifer Wright, Sales Directors for Defendant ERMI, stated to Relator, in effect, that if Defendant ERMI was audited again "it will all be over."

145. Senior personnel for Defendant ERMI have acknowledged that if Defendant ERMI was subjected to an audit by DOL or OWCP, Defendant ERMI would be shut down for fraud.

146. Defendant ERMI knowingly evades paying employment taxes and property taxes in a number of jurisdictions.

147. Defendant ERMI failed to notify Federal health insurance; workers' compensation programs; and state licensing, registration, permitting, certification and inspection authorities of Defendant ERMI's change of location of its principal place of business. During a meeting, Defendant Branch and Mikael Ohman told

persons present, including Relator, that Defendant ERMI would not be changing its address.

148. Defendant ERMI retains patients' payment card information in violation of the Payment Card Industry's Data Security Standard (PCI DSS).

149. Defendant ERMI classifies the drivers who deliver Defendant ERMI's flexionator DME as independent contractors, to whom Defendant ERMI issues United States Department of the Treasury, Internal Revenue Service Form 1099-MISC, Miscellaneous Income. Defendant ERMI made the decision to classify its drivers as independent contractors and not employees while Relator was employed by Defendant ERMI. Defendant ERMI's drivers enter the homes of patients on behalf of Defendant ERMI, however the drivers are not covered under Defendant ERMI's liability policies.

150. On or about August 24, 2019, Defendant Branch told Relator and others that their purpose at Defendant ERMI was to prepare Defendant ERMI for a capital transaction.

COUNT ONE
VIOLATIONS OF THE FALSE CLAIMS ACT,
31 U.S.C. §§ 3729, *ET SEQ*.

151. Plaintiff United States of America and Relator hereby incorporate by reference the preceding paragraphs of this False Claims Complaint as if fully incorporated and re-alleged herein.

152. As set forth above, through the actions and omissions alleged herein, Defendant ERMI and Defendant Branch, through their officers, employees, agents, or representatives, knowingly, in reckless disregard and/or in deliberate ignorance of the truth, presented, or caused to be presented, to officers, employees, or agents of the United States Government false or fraudulent claims for payment or approval, in violation of 31 U.S.C. § 3729.

153. As set forth above, through the actions and omissions alleged herein, Defendant ERMI and Defendant Branch, through their officers, employees, agents, or representatives, knowingly, in reckless disregard and/or in deliberate ignorance of the truth, made, used, or caused to be made or used, false or fraudulent records or statements material to a false or fraudulent claim, in violation of 31 U.S.C. § 3729.

154. Defendants' actions and/or omissions, and/or the false or fraudulent claims, statements and/or records, were material.

155. But for Defendants' actions and/or omissions, and/or the false or fraudulent claims, statements and/or records, the United States Government would not have paid Defendants' claims, or would have paid the claims in lesser amounts.

156. As a direct and proximate result of Defendants' actions and/or omissions, and/or the false or fraudulent claims, statements and/or records, the United States Government has suffered substantial monetary damages, and has sustained other damages, to be proven at trial.

157. Pursuant to the False Claims Act, the United States is entitled to treble damages, in an amount to be proven at trial, and a civil penalty of between $5,500.00 and $11,000.00 for each false or fraudulent claim which occurred before November 2, 2015, and between $11,665 to $23,331 for each false and fraudulent claim which occurred thereafter and assessed as of the time of this filing. Relator is entitled to at least 15 percent, but not more than 25 percent, of the proceeds of any judgment or settlement, as well as costs and reasonable attorney's fees.

COUNT TWO
REVERSE FALSE CLAIMS,
31 U.S.C. § 3729(a)(1)(G)

158. Plaintiff United States of America and Relator hereby incorporate by reference the preceding paragraphs of this False Claims Complaint as if fully incorporated and re-alleged herein.

159. As particularly set forth above, Defendant ERMI and Defendant Branch, through their officers, employees, agents, or representatives, knowingly made, used, or caused to be used, false records or statements material to an obligation to pay or transmit money or property to the Government, and/or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property to the Government.

160. Defendants' actions, omissions and/or concealment, and/or the false or fraudulent records and/or statements, were material.

161. But for Defendants' actions, omissions and/or concealment, and/or the false or fraudulent records and/or statements, the United States Government would have received greater amounts of money from Defendant ERMI.

162. As a direct and proximate result of Defendants' actions, omissions and/or concealment, and/or the false or fraudulent records and/or statements, the United States Government has suffered substantial monetary damages, and has sustained other damages, to be proven at trial.

163. Pursuant to the False Claims Act, the United States is entitled to treble damages, in an amount to be proven at trial, and a civil penalty of between $5,500.00 and $11,000.00 for each false or fraudulent claim which occurred before November 2, 2015, and between $11,665 to $23,331 for each false and fraudulent

claim which occurred thereafter and assessed as of the time of this filing. Relator is entitled to at least 15 percent, but not more than 25 percent, of the proceeds of any judgment or settlement, as well as costs and reasonable attorney's fees.

COUNT THREE
CONSPIRACY TO VIOLATE THE FALSE CLAIMS ACT,
31 U.S.C. §§ 3729, *ET SEQ.*

164. Plaintiff United States of America and Relator hereby incorporate by reference the preceding paragraphs of this False Claims Complaint as if fully incorporated and re-alleged herein.

165. Defendant ERMI and Defendant Branch conspired with others to cause false claims to be paid by the United States Government, in violation of 31 U.S.C. § 3729.

166. Defendant ERMI and Defendant Branch performed numerous acts to effect the object of the conspiracy, including repeatedly limiting Relator's authority as an officer of Defendant ERMI's Compliance Department and preventing Relator from doing her job; ordering Defendant ERMI's officers or employees not to speak with, or provide information to, Relator; and ordering Relator in the performance of her job and her responses to government agents or employees.

167. As a direct and proximate result of Defendants' actions and/or omissions, and/or the false or fraudulent claims, statements and/or records, the United States

Government has suffered substantial monetary damages, and has sustained other damages, to be proven at trial.

168. Pursuant to the False Claims Act, the United States is entitled to treble damages, in an amount to be proven at trial, and a civil penalty of between $5,500.00 and $11,000.00 for each false or fraudulent claim which occurred before November 2, 2015, and between $11,665 to $23,331 for each false and fraudulent claim which occurred thereafter and assessed as of the time of this filing. Relator is entitled to at least 15 percent, but not more than 25 percent, of the proceeds of any judgment or settlement, as well as costs and reasonable attorney's fees.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff/Relator, acting on behalf of and in the name of the United States, demand and pray that judgment be entered in favor of the United States against each Defendant, jointly and severally, as follows:

1. The amount of the United States' damages in an amount to be proven at trial;

2. Treble the amount of the United States' damages in an amount to be proven at trial;

3. Civil penalties for each false claim submitted; and

4. Reasonable costs and attorney's fees.

This 9th day of October, 2020.

/s/ Randy Edwards
R. Randy Edwards
Georgia Bar No. 241525

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LOCAL RULE 7.1D CERTIFICATION

By signature below, counsel certifies that the foregoing document was prepared in Times New Roman, 14-point font in compliance with Local Rule 5.1B.

/s/ Randy Edwards
Randy Edwards
Georgia Bar No. 241525